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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,915	11/18/2003	John Cooker	COO 20200	5654

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EXAMINER
MAEWALL, SNIGDHA

ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,915	COOKER, JOHN	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 09/02/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of IDS filed on 09/02/04 is acknowledged.

Claims 1-36 are pending in this application, claims 1-36 will be examined on the merits.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 21 and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S. Patent No. (6,656,501). Although the conflicting claims are not identical, they are not patentably

distinct from each other because claim 1 and 6 of US Patent No.(6,656,501) are directed towards an oral dosage form for human ingestion configured to be swallowed in whole with a liquid, comprising: a capsule having a first portion and a second portion attached to the first portion, each portion having an interior; an active ingredient concentrated in the interior of the first portion; and a predetermined amount of filler concentrated in the interior of and adhered to the second portion of the capsule, the filler being chosen from the group consisting of sucrose, dextrose, lactose, fructose, microcrystaline cellulose, sorbitol, xylitol, isomalt, gelatin and starch, the filler having a predetermined weight that increases the density of the capsule to a predetermined density that effects sinking of the entire capsule in the liquid, the amount and concentration of the filler being such as to eliminate formation of regions within the interior of the second portion that are relatively low density with respect to the liquid with which the capsule is swallowed; wherein the percentage of the total weight of the capsule that is due to the weight of the filler is between about 15% and 80%; and wherein the amount and concentration of the filler in the interior of the second portion significantly reduce the buoyancy of the capsule so as to cause the entire capsule to sink in the liquid, wherein said predetermined weight and concentration of the filler effect an increase in the density of the capsule to at least 1.0 g/ml.

The claims 21 and claim 23 of the instant application recite the same limitations as claim 1 and claim6 of the patented claims. The only difference is in the percentage of the digestible substance which is between 15% to 80% in the instant application. It

would have been obvious to the one of ordinary skilled in the art to optimize the percentage of the digestible substance in order to obtain the desired effect.

4. Claim 24 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/956301.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claim 1 is specific about the disclosed dosage form such as capsule for swallowing with liquid, comprising a body portion comprising an opening and an interior in communication with the opening, an active ingredient and a filler cap portion. The instant claim 24 claims a generic dosage form reciting the same limitations as claim 1 of co-pending application 10/956301. It would have been obvious to one of ordinary skilled in the art to prepare capsule based on the limitations of claim 1 of co-pending application.

5. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is drawn to an oral dosage form wherein a substance is concentrated in a particular "portion." It is unclear as to what portion the substance need be in, in other words, it is unclear what the term portion is used to connote (i.e. Weight percentage, location in the dosage).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8, 13-15, 17-20, 28-29, 32-33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherwood et al. (U.S Patent No. 5,725,884).

A microcrystalline cellulose-based excipient having improved compressibility, whether utilized in direct compression, dry granulation or wet granulation formulations, is disclosed. The excipient is an agglomerate of microcrystalline cellulose particles and from about 0.1% to about 20% silicon dioxide particles, by

weight of the microcrystalline cellulose, wherein the microcrystalline cellulose and silicon dioxide are in intimate association with each other (abstract). Another commonly used class of excipients in solid dosage forms are binders. Binders are agents which impart cohesive qualities to the powdered material(s). Commonly used binders include starch, and sugars such as sucrose, glucose, dextrose, and lactose (column 1 , page 55-60). A processed cellulose, microcrystalline cellulose, has been utilized extensively in the pharmaceutical industry as a direct compression vehicle for solid dosage forms. Micro-crystalline cellulose is commercially available under the tradename EMCOCEL.RTM..RTM. from Edward Mendell Co., Inc. and as Avicel.RTM. from FMC Corp. Compared to other directly compressible excipients, microcrystalline cellulose is generally considered to exhibit superior compressibility and disintegration properties. (column 2, lines 42-50). The present invention is further directed to a method of maintaining and/or enhancing the compressibility of microcrystalline cellulose. The method includes forming an aqueous slurry containing a mixture of microcrystalline cellulose and silicon dioxide having a particle size from about 1 nm to about 100 .mu.m, and drying the slurry to obtain microcrystalline cellulose-based excipient particles in which the silicon dioxide particles have been integrated with the microcrystalline cellulose particles. Within this aspect of the invention, the slurry contains from about 0.5% to about 25% by weight microcrystalline cellulose, with amounts of from about 15% to about 20% being preferred (column 6 lines, 10-12). Typically, microcrystalline cellulose has an apparent density of about 0.28 g/cm.sup.3 and a tap density of about 0.43 g/cm.sup.3. Handbook of Pharmaceutical Excipients,

pages 53-55 (column 7, lines 45-47). In addition to one or more active ingredients, additional pharmaceutically acceptable excipients (in the case of pharmaceuticals) or other additives known to those skilled in the art (for non-pharmaceutical applications) can be added to the novel excipient prior to preparation of the final product. For example, if desired, any generally accepted soluble or insoluble inert pharmaceutical filler (diluent) material can be included in the final product (e.g., a solid dosage form). Preferably, the inert pharmaceutical filler comprises a mono-saccharide, a disaccharide, a polyhydric alcohol, inorganic phosphates, sulfates or carbonates, and/or mixtures thereof. Examples of suitable inert pharmaceutical fillers include sucrose, dextrose, lactose, xylitol, fructose, sorbitol, calcium phosphate, calcium sulfate, calcium carbonate, "off-the-shelf" microcrystalline cellulose, mixtures thereof, and the like (column 12, lines, 23-35). The tablet can be coated (column, 12, lines 63-65). the novel excipient can be utilized in other applications wherein it is not compressed. For example, the granulate can be admixed with an active ingredient and the mixture then filled into capsules. The granulate can further be molded into shapes other than those typically associated with tablets. For example, the granulate together with active ingredient can be molded to "fit" into a particular area in an environment of use (column 15, lines 20-30). In example 7-12, the amount of microcrystalline cellulose is much more than active ingeredient.

10. Claims 1-2, 4-11, 13,14, 18, 25- 29, 33, and 35- 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (U.S Patent No.5, 198, 229).

Wong et al. teaches a capsule comprising an active agent (col. 8, lines 54 and col. 9, line 22) and excipients (col. 8, lines, 6-17). The capsule comprises a buoyancy chamber with a low density to allow the device to float within or on the surface of fluid (col. 10, 28-41). The capsule also comprises a high- density portion so that the device sinks (col. 10, lines, 42-54). The low density is in the range of from about 0.5 to about 0.7 (column 10, lines, 32-35). Wong et al. further discloses that the active agent formulation comprises the active agent to be delivered, as a liquid, solid, semisolid. It may additionally include dosage forms comprising the active agent which are capable of maintaining their physical configuration and chemical integrity while housed within the dispenser. These include, without limitation, tablets with or without a density element; matrix tablets; spheres; pellets and elongated tablets; capsules (column 7, lines, 55-65). The method of making density augmented capsule is depicted in column 11, lines 55-65).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1, 18, 21-24 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckenhoff (U.S Patent No. 5,098,425).

Eckenhoff teaches a dispensing device wherein a capsule contains a composition comprising a beneficial agent and a composition comprising a hydrogel and a denser member (column, 17, claim 1). The dense member increases the density of hydrogel composition to impart an initial density of greater than 1 to 8 (column, 10, lines 3-39). The hydrogel composition with the dense member is located at one end of the device as seen taught in the drawings of the reference. The thermo-responsive formulation and the delivery means perform in concert for dispensing a beneficial agent through passageway means to an animal over a prolonged period of time (abstract).

Eckenhoff does not expressly teach the weighting device effects of the swallowing of the device. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make a dosage form with a filler that is denser than the device substance contained in the dosage form that the filler is located in one end of the dosage form. It is obvious that if a dosage form is heavier at one end, that end will point towards the pharynx. One of ordinary skill in the art would have been motivated to do this to achieve sinking of the dosage form or retention of the device in the stomach. Hence, the invention was prima facie obvious as a whole to one of ordinary skilled in the art at the time the invention was made.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Sherwood et al. (U.S Patent No. 5,725,884) or Wong et al. (U.S Patent No.5, 198, 229). in view of Voss et al. (US patent No. 4,548,825).

The teachings of Sherwood et al. and Wong et al. have been discussed above. Sherwood et al. and Wong et al. do not disclose indicia on the tablet or capsule. Voss et al.'s disclosure relates to the non-contact printing on pharmaceutical tablets, tablet cores, and tablet-like food (abstract).

Voss et al. discloses that the safety of application of such pharmaceutical forms with indicia is increased if, for example, with regard to different doses of the same active substance, clearly visible special codings are printed on moldings to minimize confusion or if the pharmaceutical form is lettered with the specification of the quantity of active substance (column, 6, lines 40-45).

It would have been obvious to one of ordinary skilled in the art at the time the invention was made to prepare capsules with indicia because it increases the safety and also makes it visibly clear to the patient to take the correct medicine. An indicia also increases the aesthetics which would have been within the purview of a skilled artisan at the time the invention was made. A skilled artisan would thus have been motivated to prepare tablet with indicia to make it easier, safer and convenient for the patients with a reasonable expectation of success.

14. Claim 16 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherwood et al. (U.S Patent No. 5,725,884) or Wong et al. (U.S Patent No.5, 198, 229). in view of Berta (US Patent No. 4,820,524).

The teachings of Sherwood et al. (U.S Patent No. 5,725,884) and Wong et al. have been discussed above. Sherwood et al. and Wong et al. do not disclose caplet.

Berta discloses a novel capsule-like medicament, method for producing such medicaments and apparatus are disclosed. The method provides a procedure for coating solid cores, such as caplets, with gelatinous coatings to produce a shiny, capsule-like medicament. Such medicaments are achieved by individually dipping and drying first one end, and then the other end, of each caplet to provide a coating which is smoother and easier to swallow than an uncoated caplet. The production of these capsule-like medicaments is readily facilitated by simple and inexpensive modifications, which can be made to existing empty gelatin capsule making equipment (abstract).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to prepare caplets as disclosed by Berta because caplets are smoother and easier to swallow. A skilled artisan would have made caplets comprising active and inactive excipients with a reasonable expectation of success.

15. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherwood et al. (U.S Patent No. 5,725,884) or Wong et al. (U.S Patent No.5, 198, 229) in view of Ranade (US patent No. 4803076).

The teachings of Sherwood et al. (U.S Patent No. 5,725,884) and Wong et al. have been discussed above. Sherwood et al. and Wong et al. do not teach that the tablet may be formed in a conical shape. Ranade teaches a pharmaceutical tablet in the shape of a truncated cone (column, 3, lines, 9-19, column 5, lines1-9 and figures 1-4). It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to form a tablet in a shape of a cone. A skilled artisan would have been motivated to make cone shaped tablet to provide sufficient weight to remain in the stomach or reticular sac (Ranade, column, 7, lines 28-32) with a reasonable expectation of success.

16. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherwood et al. (U.S Patent No. 5,725,884) or Wong et al. (U.S Patent No.5, 198, 229) in view of chow et al. (US patent No. 4959219).

The teachings of Sherwood et al. and Wong et al. have been discussed above. Sherwood et al. and Wong et al. do not teach that the tablet may be formed in a trapezoid shape. Chow et al. teaches a pharmaceutical tablet in the shape of a trapezoid (column 5, lines 33-35).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to form a dosage form in the shape of trapezoid. A skilled artisan would have been motivated to prepare a tablet in a trapezoid because it has more aesthetics and has more weight in one part of the tablet or dosage form. Hence, a

skilled artisan would have been prepared a tablet of trapezoid form with a reasonable expectation of success.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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1615

/Shubha/

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